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1420 FIFTH AVENUE		LAM, ANN Y		
SUITE 2800	'A 98101-2347		ART UNIT PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		T	<u>,                                    </u>
		Application No.	Applicant(s)
		10/630,235	RATNER ET AL.
	Office Action Summary	Examiner	Art Unit
	· · · · · ·	Ann Y. Lam	1641
Period fo	The MAILING DATE of this communication app r Reply	ears on the cover sheet with the c	correspondence address
WHIC - Exten after: - If NO - Failur Any re	DRTENED STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DA sions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period w e to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing d patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from cause the application to become ARANDONE	N. nely filed  the mailing date of this communication. D. (35 U.S.C. § 133)
Status			
1)	Responsive to communication(s) filed on 28 No	ovember 2006.	
		action is non-final.	
3)	Since this application is in condition for allowar		secution as to the merits is
	closed in accordance with the practice under E		
ispositi	on of Claims		
5)□ 6)⊠ 7)□	Claim(s) <u>1-47</u> is/are pending in the application.  4a) Of the above claim(s) <u>16-47</u> is/are withdraw  Claim(s) is/are allowed.  Claim(s) <u>1-15</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or		
	on Papers		
• •	he specification is objected to by the Examiner		
	The drawing(s) filed on <u>29 July 2003</u> is/are: a)		by the Examiner
	Applicant may not request that any objection to the c		
	Replacement drawing sheet(s) including the correcti		* *
	he oath or declaration is objected to by the Exa		• •
riority u	nder 35 U.S.C. § 119		
a)[	Acknowledgment is made of a claim for foreign    All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents	have been received.	
	<ul><li>2. Certified copies of the priority documents</li><li>3. Copies of the certified copies of the priori</li></ul>		
•	application from the International Bureau		u iii iiiis ivalionai Stage
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	of References Cited (PTO-892)	4) Interview Summary (	(PTO-413)
Notice	of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal Pa	te
	ation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	6) Other:	асель друнсацоп

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#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election of Group I as well as the species poly(N-isopropylacrylamide) in the reply filed on November 28, 2006 and June 9, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### Status of Claims

Claims 16-47 are withdrawn.

Claims 1-15 are currently pending.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 1-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takei et al. "Dynamic Contact Angle Measurement of Temperature-Responsive Surface Properties for Poly(N-isopropylacrylamide) Grafted Surfaces", Macromolecules 1994, 27, 6163-6166, in view of Carlson et al., 6,939,515.

As to claim 1, Applicants claim a device for binding cells or molecules, wherein the device comprises: a body defining a first surface and a second surface that is located opposite to the first surface; a heater disposed upon the first surface; and a temperature-responsive layer disposed upon the second surface, wherein the temperature-responsive layer comprises a temperature-responsive material that can exist in a first state that binds molecules or living cells, and can exist in a second state that binds substantially less molecules or living cells than the first state, and wherein the temperature-responsive material is reversibly convertible to the first state from the second state in response to an effective amount of thermal energy.

Takei et al. teach that poly(N-isopropylacrylamide) exhibits large swelling changes in aqueous media in response to small changes in temperature and that temperature-responsive properties of poly(N-isoproplyamide) have been utilized in a variety of applications including controlled drug delivery and solute separation. Takei et al. teach that poly(N-isopropylamide) grated on solid substrates caused temperature-dependent surface properties and that on these surfaces. Poly(N-isopropylacrylamide) on polystyrene dishes were utilized as cell culture substrates and on these surfaces, controlled cell attachment-detachment could be achieved using the reversible hydration-dehydration phenomena of these polymer chains by changing temperature (page 6163, left column.) Thus, Takei et al. teach a temperature-responsive layer, i.e., poly(N-isopropylamide) which can exist in a first state that binds living cells and can exist in a second state that binds less living cells (see disclosure of cell culture and cell-attachment and detachment.)

However while Takei et al. teach an external stimulus that causes a change of temperature which alters the properties of the temperature-responsive material, and specifically disclose that in the experiment, the temperature of circulating water and atmosphere in the measurement chamber was well-controlled (page 1664, right column, under "Dynamic Contact Angle Measurement" heading), Takei et al. do not specifically teach a heater disposed upon a first surface that is located opposite to the surface on which the temperature-responsive material is disposed, as is claimed by Applicants in claim 1.

Carlson et al. however teach an assay device that includes a thermal platform (2810) that can support and controllably heat an array (i.e., a substrate containing samples) (col. 55, lines 6-8, and see fig. 28). Carlson et al. teach that the platform (2810) includes a thermal platform top (2812) and thermal platform base (2814), which when assembled together create a cavity (2816) that supports a substrate or suitable testing platform (e.g., a carrier plate), (col. 55, lines 11-14). Moreover it is taught by Carlson et al. that the heating elements (2822) may be attached to or embedded in the thermal platform base (2814) to provide a mechanism for heating thermal platform base (2814), (col. 55, lines 64-67). Carlson et al. teach that resistive heating elements (2822) may be embedded or attached to thermal platform base (2814) to permit improved control of thermal control of thermal uniformity or specific temperature profiles in thermal platform (281), (col. 56, lines 3-12). Carlson et al. teach for example that the temperature of the thermal platform containing the substrate and material samples is increased at a defined rate and monitored with one or more temperature sensors in

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contact with the substrate and that a computer can be interfaced with the heating system to provide feedback for better temperature control (col. 58, lines 7-15).

Thus, Carlson et al. teach a device with a heater disposed on one surface (i.e., 2814) that is located opposite to the surface on which material samples are located (i.e., the substrate or testing platform disclosed in column 55, lines 13-14), (see figure 28). While Takei et al. teach an external stimulus providing a temperature change but does not disclose the location of the external stimulus with respect to the temperatureresponsive material nor any structural details as to this external stimulus, nevertheless it is understood that there is an external stimulus that provides a temperature change. Moreover, Carlson et al. teach a device equipped with a heating element to heat the substrate containing material sample for an assay. Carlson et al. also teach that the device provides the advantage of improved thermal control of thermal uniformity or specific temperature profiles in thermal platform (col. 56, lines 3-12), and that the temperature of the thermal platform containing the substrate and material samples can be increased at a defined rate and monitored with one or more temperature sensors that is interfaced with a computer to provide feedback for better temperature control (col. 58, lines 7-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a heating element opposite the substrate on which the temperature-responsive material disclosed by Takei et al. is disposed, as taught by Carlson et al., as the specific external stimulus generally disclosed by Takei et al., because Carlson et al. teach that the heating elements in this configuration provides the advantage of improved thermal control of thermal uniformity or specific temperature

profiles in thermal platform. Moreover Carlson et al. teach that a further advantage of the heating system includes better temperature control through a temperature monitor and a computer for feedback. Thus it would have been obvious to one of ordinary skill in the art to utilize the heating system in the configuration taught by Carlson et al. as the specific external stimulus that is only generally disclosed by Takei et al. particularly in view of the advantages of the heating system taught by Carlson et al. Thus, given the modifications to the Takei et al. invention as taught by Carlson et al., the substrate on which the heating elements are disposed is deemed to be the first surface and the substrate on which the temperature-responsive material is disposed is deemed to be second surface, as are claimed by Applicants.

As to claim 2, the body consists essentially of glass (see Takei et al., page 6164, bottom of left column.)

As to claims 3 and 5, Takei et al. teach that the glass substrate is 24X50 mm in area and 0.2 mm in thickness (page 6164, bottom of left column), which thus falls within the ranges recited by Applicants.

As to claim 4, Takei et al. teach that the glass slide is 24 mm X 50 mm (which is 12 cm<sup>2</sup>) and thus do not specifically teach that the glass slide has an area of 1.0 mm<sup>2</sup> to 5.0 cm<sup>2</sup>. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Takei et al. and Carlson et al. teach the general conditions of the claims (with Takei et al. teaching a substrate with a temperature-responsive material and Carlson et al. teaching a heating element

disposed opposite a substrate containing material samples), and thus discovering the workable or optimum range in dimensions of the substrate and heating element involves only routine skill in the art under *In re Aller*.

As to claim 6, Takei et al. teach that the glass substrate is 24X50 mm in area and 0.2 mm in thickness (see Takei et al., page 6164, bottom of left column), which is a rectangular shape of substrate recited by Applicants. As to the shape of the first surface (i.e., heating surface), while Carlson et al. do not disclose the shape of the substrate on which the heating elements are disposed, it would have been an obvious matter of design choice to form the first surface and second surface in rectangular shape, since such a modification would have involved a mere change in the shape of a component and would also complement the shape of the second surface, i.e., the surface to be heated. A change in shape is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)

As to claim 7, Applicants claim that the first surface and the second surface are both square. While neither Takei et al. nor Carlson et al. that disclose that the shape of the glass substrate and the substrate on which the heating elements are disposed is square, it would have been an obvious matter of design choice to form the first surface and second surface in square shapes, since such a modification would have involved a

mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

As to claims 8 and 9, the temperature-responsive material is poly(Nethylmethacrylamide) (see Takei et al., page 6163, left column.)

As to claim 10, Applicants claim that multiple heaters are disposed upon the first surface. Takei et al. teach that temperature of circulating water and atmosphere in the measurement chamber was well-controlled (right column, under "Dynamic Contact Angle Measurement" section). Moreover, Carlson et al. teach multiple heaters (2822), (see fig. 28, and col. 55, line 64) to individually heat materials in different chambers. Thus, Carlson et al. teach multiple heaters. As indicated above regarding the discussion of claim 1, given the modifications to the Takei et al. invention as taught by Carlson et al., the substrate on which the heating elements are disposed is deemed to be the first 1surface and the substrate on which the temperature-responsive material is disposed is deemed to be second surface, as are claimed by Applicants.

As to claims 11 and 14, a living cell is attached to the temperature-responsive layer (see in Takei et al. reference the disclosure of cell culture and cell-attachment and detachment, page 6163, left column.) As to the location of the living cell opposite the heater, this has been discussed above regarding Carlson et al. (a heater disposed on one surface, 2814, that is located opposite to the surface on which material samples are located, i.e., the substrate or testing platform disclosed in column 55, lines 13-14, and see figure 28.) The substrate on which the heating elements are disposed, as taught by

Carlson et al., is deemed to be the first surface and the substrate on which the temperature-responsive material is disposed is deemed to be the second surface, as claimed by Applicants. Moreover, Carlson et al. teach multiple heaters (2822), (see fig. 28, and col. 55, line 64). The first two heaters (2822) disclosed by Carlson et al. in figure 28 are deemed to form a first population of heaters, and the next two heaters are deemed to form a second population of heaters. As shown by Carlson et al. in figure 28, the heaters are located opposite the testing platform. The portions of temperatureresponsive layer that are opposite the first population of heaters is deemed to be the first population of portions, and the portions of temperature-responsive layer that are opposite the second population of heaters is deemed to be the second population of portions.

2. Claims 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takei et al. "Dynamic Contact Angle Measurement of Temperature-Responsive Surface Properties for Poly(N-isopropylacrylamide) Grafted Surfaces", Macromolecules 1994, 27, 6163-6166, in view of Carlson et al., 6,939,515, as applied to claim 1 above, and further in view of Lahann et al., 7,020,355

Takei et al. in view of Carlson et al. disclose the invention substantially as claimed (see above).

Takei et al. teach that poly(N-isopropylacrylamide) exhibits large swelling changes in aqueous media in response to small changes in temperature and that

temperature-responsive properties of poly(N-isoproplyamide) have been utilized in a variety of applications including controlled drug delivery and solute separation. Takei et al. teach that poly(N-isopropylamide) grated on solid substrates caused temperature-dependent surface properties and that on these surfaces, controlled cell attachment-detachment could be achieved using the reversible hydration-dehydration phenomena of these polymer chains by changing temperature (page 6163, left column.) Takei et al. also teach that end-functionalized poly(N-isopropylacrylamide) will display the largest change in surface properties with change in temperature (page 6163, top of right column.)

While Takei et al. teach controlled cell attachment and detachment on poly(N-isopropylacrylamide) using change in temperature, Takei et al. however do not teach attachment of protein molecules, e.g., antibodies, on the poly(N-isopropylacrylamide).

Lahann et al. teach that self-assembled monolayers have been used to control and pattern the properties of a variety of surfaces and Lahann et al. disclose that it has been found that the wetability of a surface may be controlled by changing the temperature around the lower critical solution temperature of poly(N-isopropylacrylamide)-grafts (col. 1, lines 48-58, citing Takei et al.) Lahann et al. teach that however there is very little research concerning controlled switching between different surface properties (col. 1, lines 49-51). Lahann et al. further state that accordingly it is desirable to develop a method by which the surface properties of a self-assembled monolayer structure may be reversibly switched upon application or removal of an external force field (col. 1, lines 61-64). Then Lahann et al. teach the disclosed

invention comprising a nanolayer that shifts from a first conformation state to a second conformation state upon application of an external stimulus (col. 2, lines 38-40), wherein the external stimulus may be a change in temperature (col. 2, lines 51-53), and Lahann et al. teach reversibly modifying the property of the nanolayer by application of the stimulus to shift the nanolayer from a first absorption affinity to a second absorption affinity, such as an affinity for an analyte (col. 3, lines 40-50).

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Thus, Lahann et al. teach that controlling properties of a variety of surfaces are known and Lahann et al. specifically give an example of poly(N-isopropylacrylamide) as a material in which wetability may be controlled by changing temperature. It is noted that Lahann et al. teach that the wetting behavior is defined by the molecular-level structure of the interface (col. 5, lines 5-8, and see lines 30-33). Lahann et al. then teach use of such materials, more specifically, Lahann et al. teach reversibly modifying the properties of such materials by an external stimulus for assay purposes such as concentrating analyte or detecting small quantities of analyte (see col. 24, lines 17-28). Thus, while Lahann et al. do not specifically teach the use of poly(Nisopropylacrylamide) in the disclosed invention, Lahann et al. teach, in general, use of a material that is responsive to temperature (col. 2, lines 51-53), and that a variety of materials that can be controlled are known, including poly(N-isopropylacrylamide), a material in which wetability may be controlled by changing the temperature (col. 1, lines 51-56). However, Lahann et al. specifically teach that the temperature-responsive material (nanolayer) can be constructed to facilitate adhesion of cells and biomolecules in one conformation and to repel the adhered material or to change the organization of

deposited biomolecules in a second conformation (col. 13, line 59 – col. 14, line 3); the term "biomolecules" used by Lahann et al. refers to molecules including proteins and antibodies (col. 4, lines 43-44 and 53.) Lahann et al. further teach that the temperature-responsive nanolayer can be used to facilitate cell attachment for culture, and attachment of analyte and release for detection (col. 24, lines 4-28.)

It is emphasized that Lahann et al. teach that the nanolayer, i.e., a temperature-responsive material, can attach and detach antibodies with a change in conformation and also disclose poly(N-isopropylacrylamide) as a type of temperature-responsive material (citing Takei et al.), and Takei et al. teach that end-functionalized poly(N-isopropylacrylamide) will display the largest change in surface properties with change in temperature (page 6163, top of right column). It appears from the Takei et al. reference that the poly(N-isopropylacrylamide) material can attach and detach materials due to its change in conformation, i.e., surface properties. Takei et al. specifically teach that poly(N-isopropylacrylamide) have been utilized in a variety of applications including controlled drug delivery and solute separation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize poly(N-isopropylacrylamide) taught by Takei et al. to attach antibodies because Lahann et al. teach that temperature-responsive materials provide the benefit of attaching analyte (i.e., biomolecules) and detaching for detection. The skilled artisan would understand the significance of detecting antibodies as analytes as such biomolecules are detected widely in the art for various diagnostic and medical purposes.

Moreover, the skilled artisan would have reasonable expectation of success in utilizing poly(N-isopropylacrylamide) to attach and detach antibodies since both the teachings of Lahann et al. and Takei et al. teach that a change in surface properties, or conformation, of temperature-responsive material facilitates attachment and detachment of biological materials to the temperature-responsive material, and Takei et al. also teach that poly(N-isopropylacrylamide) has been utilized in a variety of applications including controlled drug delivery and solute separation, which further suggest that poly(N-isopropylamide) can bind to molecules such as antibodies.

As to claim 15, Applicants claim that the multiple heaters comprise a first population of heaters and a second population of heaters, and the temperature-responsive layer comprises a first population of portions, located opposite the first population of heaters, and a second population of portions, located opposite the second population of heaters, wherein a first type of protein molecules is attached to the first population of portions, and a second type of protein molecules is attached to the second population of portions.

The substrate on which the heating elements are disposed, as taught by Carlson et al., is deemed to be the first surface and the substrate on which the temperature-responsive material is disposed is deemed to be the second surface, as claimed by Applicants. Moreover, Carlson et al. teach multiple heaters (2822), (see fig. 28, and col. 55, line 64). The first two heaters (2822) disclosed by Carlson et al. in figure 28 are deemed to form a first population of heaters, and the next two heaters are deemed to form a second population of heaters. As shown by Carlson et al. in figure 28, the

heaters are located opposite the testing platform. The portions of temperatureresponsive layer that are opposite the first population of heaters is deemed to be the first population of portions, and the portions of temperature-responsive layer that are opposite the second population of heaters is deemed to be the second population of portions. In the combination of the teachings of Takei et al. and Lahann et al. as discussed above, the protein that is attached to the first population of portions is deemed to be to be a first type of protein, as is claimed by Applicants, and the protein that is attached to the second population of portions is deemed to be a second type of protein (since Applicants do not specify that the first and second type of proteins are different from each other.) (Alternatively, while neither Takei et al. nor Lahann et al. teach different types of proteins in a population of wells or chambers, Carlson teach that this is known in the art to allow for different assays to be performed (col. 25, line 56 – col. 26, line 4), and the skilled artisan would have recognized the benefit of convenience in performing different assays in one substrate as well as the convenience in performing simultaneous assays using different proteins (as regards Applicants' claim 15), or different living cells (as regards Applicants' claim 14.)

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## Response to Arguments

Applicants' arguments filed November 28, 2007 have been fully considered but they are not persuasive. Applicants assert that claim 1 has been amended to clarify that the device of the claimed invention comprises a temperature-responsive film that is

deposited by plasma deposition. Applicants argue that the types of films produced by the Lahann et al. self-assembled monolayer (SAM) technique and the plasma deposition technique of the present invention are entirely different. Applicants state that SAM molecules are characterized by having head groups that strongly bond to a substrate and tail groups that form strong interactions and that SAMs are limited in molecular length because of the latter requirement, and a polymer, such as poly(Nisopropylamide) will not form a SAM because it does not have a known SAM-forming head group and the length of a polymer will generally exclude it from satisfying the necessary SAM-forming tail-group properties. Applicants argue that because poly(Nisopropylamide) cannot form a SAM film, there is not a reasonable expectation of success of combining the known temperature-responsive material poly(Nisopropylamide) with the teachings of Lahann et al. Applicants assert that in sharp contrast, the plasma deposition-coated devices of Applicants' amended claims will not produce SAM films because of the isotropic nature of the plasma deposition process and the larger molecular weight molecules used in the technique.

These arguments are moot in view of the new ground(s) of rejection which cites Takei et al. as the primary reference. However, since the Takei et al. reference was relied upon by the Lahann et al. reference (previously the primary reference) and the Lahann et al. reference also cited the Takei et al. reference, Applicants' arguments will be addressed.

Applicants' argument appears to be that the poly(N-isopropylacrylamide) is not capable of being used for binding to cells and converting to a second state in which it

binds less cells in response to thermal energy. However this is contradicted by the Takei et al. reference which specifically teaches that poly(N-isopropylacrylamide) is used for controlled cell attachment and detachment by changing temperature. The Lahann et al. reference is only relied upon in the current Office action for the teachings of binding proteins, and in particular antibodies, to modify the Takei et al. reference, which is described in the grounds for rejection above and thus will not be repeated here. The Lahann et al. reference is not relied upon in the present Office action for the teaching of poly(N-isopropylacrylamide), but rather the Takei et al. reference is used to show that this material is known for the properties recited by Applicants.

### Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ANN YEN LAM
PATENT EXAMINER